510(k) Summary

Contreet Foam Dressing

FEB 0 3 2003

Submitters name, address, phone and fax numbers

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Contact person at Coloplast Corp

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Date 510(k) prepared

June 14, 2002

Name of the medical device

Trade name	Contreet Foam Dressing, Adhesive and non-adhesive
Common name	Topical wound dressing
Classification name	Dressing, wound and burn, occlusive (21CFR878.4020)

Legally marketed device to which substantial equivalence is claimed

Biatain Foam Adhesive Dressing (K983173)
Biatain Foam Non-adhesive Dressing (K983163)
Acticoat Moisture Control Dressing (K010447)

Description of the device

Contreet Foam Dressing is a wound dressing with silver as the active component. The dressing provides an optimal moist wound healing environment, combining an effective antibacterial barrier activity with exudates management.

Contreet Foam Non-adhesive is suitable for use on fragile skin due to the absence of adhesive. The film backing is waterproof and semi permeable.

Contreet Foam Adhesive has a hydrocolloid adhesive border and a central absorbent foam pad containing silver. The film backing is waterproof and semi permeable.

The dressing demonstrates in-vitro antibacterial activity for up to 7 days in certain strains known to be detrimental to wound healing such as Pseudomonas aeruginosa, Staphylococcus aureus, B-haemolytic Streptococcus, MRSA and VRE.*

*The list of bacteria that Contreet Foam has demonstrated in-vitro antibacterial activity towards is as follows: Acinetobacter, C. albicans, C. perfringens, E. cloacae, E. faecalis, E. faecium, E. coli, hemolytic Streptococcus Gr.A, MRSA (Methicillin resistant S. aureus), anaerobic Peptostreptococcus , P. mirabilis, P. vulgaris, P. aeruginosa, S. aureus, Coagulase negative Staphylococcus, S. epidermidis, VREF (Vancomycin resistant E. faecium).

Intended use of the device

Contreet Foam is an effective barrier to bacterial penetration in wounds.

Contreet Foam is indicated for exuding wounds, preferably for the management of wounds with moderately to high amounts of exudates.

Contreet Foam is indicated for partial and full thickness wounds, leg ulcers and pressure sores. The dressing can also be used for 2nd degree burns, donor sites, postoperative wounds and skin abrasions.

Contreet Foam Non-Adhesive dressing is additionally indicated for diabetic foot ulcers.

Contreet Foam can also support reduction of the odor caused by microorganisms from the wound.

Contreet Foam can be used on patients with wound infection at the discretion of the physician.

Contreet Foam is suitable for use where compression bandaging is indicated.

Summary of technological characteristics of subject device compared to predicate

Contreet Foam compared to Biatain Foam Dressings: Biatain Foam Dressings are PU-foam dressings and are the products that Contreet Foam is based on. The only difference is that Contreet Foam has silver incorporated into it. The indications for use that apply to Biatain also apply to Contreet Foam.

Contreet Foam compared to Acticoat Moisture Control Dressing: Both dressings contain silver, which acts as an antimicrobial barrier.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 3 2003

Coloplast Corporation
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Re: K022416
Trade/Device Name: Contreet Foam Adhesive/Non-Adhesive
Regulation Number: Unclassified
Regulation Name: Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 11, 2002
Received: November 18, 2002

Dear Ms. Boots:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of indications for use

510(k) Number (if known): K022416

Device Name: Contreet Foam Adhesive
Contreet Foam Non-Adhesive

Indications for Use:

The Contreet Foam is indicated for use in the management of moderately to highly exuding leg ulcers and pressure sores. The dressing can also be used for 2nd degree burns, donor sites, post operative wounds and skin abrasions. Contreet Foam Non-adhesive is additionally indicated for diabetic foot ulcers.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022416